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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of

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Complete If Known

Application Number	09/869,612
Filing Date	July 2, 2001
First Named Inventor	GIANNI
Group Art Unit	1647
Examiner Name	Pozia Hamud
Attorney Docket Number	GIANNI-1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
EH	AD	Patent Abstracts of Japan, MIZUCHI et al., "Pharmaceutical Agent For Thrombocytopenia", Publication No. 07-101877, Publication Date April 18, 1995	
	AE	TIAN et al., "Recombinant Human Growth Hormone Promotes Hematopoietic Reconstitution after Syngeneic Bone Marrow Transplantation in Mice", (1998), <u>Stem Cells</u> , vol. 16, pp. 193-199	
	AF	BREGNI et al., "Comparative Effects of Granulocyte-Macrophage Colony-Stimulating Factor and Granulocyte Colony-Stimulating Factor After High-Dose Cyclophosphamide Cancer Therapy", (1996), <u>Journal of Clinical Oncology</u> vol. 14, No. 2, pp. 628-635	
	AG	MURPHY et al., "Growth Hormone Exerts Hematopoietic Growth-Promoting Effects in Vivo and Partially Counteracts the Myelosuppressive Effects of Azidothymidine", <u>BLOOD</u> , (1992), vol. 80, No. 6, pp. 1443-1447	
	AH	MURPHY et al., "Human growth hormone promotes engraftment of murine or human T cells in severe combined immunodeficient mice", (1992), <u>Proc. Natl. Acad.</u> , vol. 89, pp. 4481-4485	
	AI	MIYAHITA, The effect of Growth Hormone on Leukopoiesis in vivo and vitro studies", (1991), <u>Folia endocrinol.</u> , vol. 67, pp. 785-795	
	AJ	KORBLING et al., "Allogeneic peripheral blood stem cell transplantation using normal patient-related pediatric donors", (1996), <u>Bone Marrow Transplantation</u> , vol. 18, pp. 885-890	
	AK	OHMIZONO et al., "Thrombopoietin augments ex vivo expansion of human cord blood-derived hematopoietic progenitors in combination with stem cell factor and flt3 ligand", (1997), <u>Leukemia</u> , vol. 11, pp. 524-530	
	AL	ADELMAN et al., "In vitro Deletional Mutagenesis for Bacterial Production of the 20,000-Dalton Form of Human Pituitary Growth Hormone", (1983), <u>DNA</u> , vol. 2, No. 3, pp. 183-193	
	AM	ALBERTSSON-WIKLAND et al., "Daily Subcutaneous Administration of Human Growth Hormone in Deficient Children", (1986), <u>Acta Paediatr Scand</u> , vol. 75, pp. 89-97	
	AN	ALEXANDER, "Cytokines in Hematopoiesis", (1996), <u>Intern Rev. Immunol.</u> , vol. 16, pp. 651-682	
	AO	ANDERLINI et al., "The Use of Mobilized Peripheral Blood Stems from Normal Donors for Allografting", (1997), <u>Stem Cells</u> , vol. 15, pp. 9-17	

Examiner
Signature

Pozia Hamud

Date
Considered

10/17/03

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¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/869,612
		Filing Date	July 2, 2001
		First Named Inventor	GIANNI
		Group Art Unit	1647
		Examiner Name	Foria Hamud
		Attorney Docket Number	GIANNI=1
Sheet	3	of	6

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ²	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
FH	AP	BECKER et al., "Chemical, Physical and Biological Characterization of a Dimeric Form of Biosynthetic Human Growth Hormone", (1987), <u>Biotechnology and Applied Biochemistry</u> , vol. 9, pp. 478-587	
FH	AQ	BECKER et al., "Isolation and Characterization of a Sulfoxide and a Desamido Derivative of Biosynthetic Human Growth Hormone", (1988), <u>Biotechnology and Applied Biochemistry</u> , vol. 10, pp. 326-337	
	AR	KOTZMANN et al., "The influence of growth hormone substitution therapy on erythroid and myeloid progenitor cells and on peripheral blood cells in adult patients with growth hormones deficiency", (1996), <u>European Journal of Clinical Investigations</u> , vol. 26, pp. 1175-1181	
	AS	WEAVER et al., "Stem cell factor leads to reduce blood processing during apheresis or the use of whole blood aliquots to support dose-intensive chemotherapy", (1998), <u>Bone Marrow Transplantation</u> , vol. 22, pp. 33-38	
	AT	WATERS et al., "Economic analyses of bone marrow and blood stem cell transplantation for leukemias and lymphoma: what do we know?", (1998), <u>Bone Marrow Transplantation</u> , vol. 21, pp. 641-644	
	AU	VIHERVUORI et al., "Hemoglobin Level Is Linked to Growth Hormone-Dependent Proteins in Short Children", (1996), <u>BLOOD</u> , vol. 87, No. 5, pp. 2075-2081	
	AV	VAN HOEF, "Haematological recovery after high-dose consolidation chemotherapy with peripheral blood progenitor cell rescue: the effects of the mobilization regimen and post-transplant growth factors", (1998), <u>The Netherlands Journal of Medicine</u> , vol. 52, pp. 30-39	
	AW	VALERIO et al., "Assessment of Red Blood Cells Indices in Growth-Hormone-Treated Children", (1997), <u>Hormone Research</u> , vol. 47, pp. 62-66	
	AX	BIK TO et al., "Single High Doses of Cyclophosphamide Enable to Collection of High Numbers of Hemopoietic Stem Cells from the Peripheral Blood",	
	AY	THORLACIUS-USSING, "Zinc in the Anterior Pituitary of Rat A Histochemical and Analytical Work", (1987), <u>Neuroendocrinology</u> , vol. 45, pp. 233-242	
	AZ	BEWLEY et al., "The Chemistry of Human Pituitary Growth Hormone", <u>Advances in Enzymology and Related Areas of Molecular Biology</u> , (1975), vol. 42, pp. 73-166	
	BA	CUNNINGHAM et al., "Dimerization of Human Growth Hormone by Zinc", <u>SCIENCE</u> , (1991) vol. 253, pp. 545-548	

Examiner Signature	Foria Hamud	Date Considered	10/17/03
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4

of 6

Complete if Known

Application Number	09/869,612
Filing Date	December 30, 1999
First Named Inventor	Alessandro Massimo GIANNI
Group Art Unit	1649
Examiner Name	Forre Hand
Attorney Docket Number	GIANNI=1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
FH	BB	STOLAR et al., "Big Growth Hormones Forms in Human Plasma: Immunochemical Evidence for Their Pituitary Origin", <u>Metabolism</u> , (1986), vol. 35, No. 1, pp. 75-77	
	BC	STOLAR et al., "Plasma "Big" and "Big-Big" Growth Hormone (GH) in Man: AN Oligomeric Series Composed of Structurally Diverse GH Monomers", <u>Journal of Clinical Endocrinology and Metabolism</u> , (1984), vol. 59, No. 7, pp. 212-218	
	BD	SINGH et al., "Modified Forms of Human Growth Hormone with Increased Biological Activities", <u>Endocrinology</u> , (1974), vol. 94, pp. 883-891	
	BE	SIENA et al., "Flow Cytometry for Clinical Estimation of Circulating Hematopoietic Progenitors for Autologous Transplantation in Cancer Patients", <u>BLOOD</u> , (1991), vol. 77, No. 2, pp. 400-409	
	BF	SIENA et al., "Circulation of CD34+ Hematopoietic Stem Cells in the Peripheral Blood of High-Dose Cyclophosphamide-Treated Patients: Enhanced by Intravenous Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor", <u>BLOOD</u> , (1989), vol. 74, No. 6, pp. 1905-1914	
	BG	MOORE et al., "Equivalent Potency and Pharmacokinetics of Recombinant Human Growth Hormones with or without an N-Terminal Methionine", <u>Endocrinology</u> , (1988), vol. 122, No. 6, pp. 2920-2926	
	BH	MERCHAV et al., "Enhancement of erythropoiesis in vitro by human growth hormone is mediated by insulin-like growth factor I", <u>British Journal of Haematology</u> , (1988), vol. 70, pp. 267-271	
	BI	LEWIS et al., "Enhancement of the Hyperglycemic Activity of Human Growth Hormone by Enzymic Modification", <u>Endocrinology</u> , (1977), vol. 101, pp. 1587-1603	
	BJ	LEWIS et al., "Altered Proteolytic Cleavage of Human Growth Hormone as a Result of Deamidation", <u>The Journal of Biological Chemistry</u> , (1981), vol. 256, No. 22, pp. 11645-11650	
	BK	LEWIS et al., "Human Growth Hormone: Additional Members of the Complex", <u>Endocrinology</u> , vol. 104, No. 5, pp. 1256-1265	
	BL	LEWIS et al., "An Interchain Disulfide Dimer of Human Growth Hormone", <u>The Journal of Biological Chemistry</u> , (1977), vol. 252, No. 11, pp. 3697-3702	
	BM	LARSSON et al., "Faster engraftment but no reduction in infectious complications after peripheral blood stem cell transplantation compared to autologous bone marrow transplantation", <u>Support Care Cancer</u> , (1998) vol. 6, pp. 378-383	

Examiner Signature	Forre Hand	Date Considered	10/17/03
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5

of 6

Application Number	09/869,612
Filing Date	July 2, 2001
First Named Inventor	GIANNI
Group Art Unit	1647
Examiner Name	Fornhamud
Attorney Docket Number	GIANNI=1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
FH	BN	KIMATA et al. "Effect of Growth Hormone and Insulin-Like Growth factor-I on Immunoglobulin Production by Growth of Human B Cells", <u>Journal of Clinical Endocrinology and Metabolism</u> , (1994), vol. 78, No. 3, pp. 635-641	
	BO	JORGENSEN et al. "Pharmacokinetics of Biosynthetic and Pituitary Human Growth Hormones in Rats," <u>Pharmacology & Toxicology</u> , (1998), vol. 63, pp. 129-134.	
	BP	JORGENSEN et al. "Serum Profiles and Short-term Metabolic Effect of Pituitary and Authentic Biosynthetic Human Growth Hormone in Man," <u>Acta Endocrinologica</u> , (1987), vol. 116, pp. 381-386.	
	BQ	HENRY. "Haematological Toxicities Associated With Dose-Intensive Chemotherapy, the Role for and Use of Recombinant Growth Factors," <u>Annals of Oncology</u> (1997), 8 (Suppl. 3): S7-S10, pp. 7-10.	
	BR	HENDRICKS et al. "Plasma Clearance of Intravenously Administered Pituitary Human Growth Hormone: Gel Filtration Studies of Heterogeneous Components," (1985), vol. 60, No. 5, pp. 864-867.	
	BS	SUTHERLAND et al. "Characterization and Partial Purification of Human Marrow Cells Capable of Initiating Long-Term Hematopoiesis In Vitro," <u>Blood</u> (October, 1989), vol. 74, No. 5, pp. 1563-1570.	
	BT	GOEDEL et al. "Direct Expression in <i>Escherichia coli</i> of a DNA sequence Coding for Human Growth Hormone," <u>Nature</u> , (October, 1979), vol. 281, pp. 544-548.	
	BU	GIANNI et al. "Rapid and Complete Hemopoietic Reconstitution Following Combined Transplantation of Autologous Blood and Bone Marrow Cells. A Changing Role for High Dose Chemo-Radiotherapy?" <u>Hematological Oncology</u> , (1989) vol. 7, pp. 139-148.	
	BV	GEFFNER. "Effects of Growth Hormone and Insulin-Like growth Factor I on T- and B-Lymphocytes and Immune Function," <u>Acta Paediatr Suppl.</u> , (1997) 423: pp. 76-79.	
	BW	GERTLER et al. "Inhibition of Lactogenic Activities of Ovine Prolactin and Human Growth Hormone (hGH) by a Novel Form of a Modified Recombinant hGH*," <u>Endocrinology</u> (1986) vol. 118, No.2, pp. 720-726.	
	BX	FISCHER et al. "Stem Cell Transplantation for Immunodeficiency," <u>Springer Semin Immunopathol</u> , (1998) 19: pp. 479-492.	
	BY	BEATA et al. "Human Rekombinans Novekedi Hormon Hatasa Egeszseges es Uraemias Gyermeke Lymphocytas Granulocyt Funkcioira In Vitro," <u>Orvosi Hetilap</u> (1998) 139 (31), pp. 1847-1850.	X

Examiner Signature	Fornhamud	Date Considered	10/12/03
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Page 6 of 1

FI2	BZ	DE NOTO et al. "Human Growth Hormone DNA Sequence and mRNA Structure: Possible Alternative Splicing," (April, 1981) vol. 9, pp. 3718-3731.	

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